TEXAS A&M UNIVERSITY KINGSVILLE	SOP: Pre-Review	
	Section III: IRB Protocols	
	Number	Date
	IRB III-002	9/13/2025

1. PURPOSE

1.1. This SOP outlines the process to pre-review a request for approval, approval of new research, continuing review of research, or modification to previously approved research. It also covers determinations regarding whether an activity is exempt Human Research, is not Human Research, or is Human Research that does not engage the institution.

1.2. This procedure begins when the IRB receives a submission requesting review and approval or a determination, including requests from external institutions when the TAMUK IRB serves as the IRB of record for a collaborative or multi-site study.

1.3. This procedure concludes when the submission has been placed on the agenda for the Convened meeting or reviewed and/or approved through a non-committee review.

2. REVISION FROM PREVIOUS VERSIONS

2.1. None

3. SOP STATEMENT

3.1. As part of IRB review, all submissions are pre-reviewed by the research compliance staff assigned to the IRB for technical concerns and then assigned to a reviewer.

4. RESPONSIBILITIES

4.1. The research compliance staff assigned to the IRB carries out these procedures.

5. PROCEDURE

5.1. Pre-Review to screen submission materials:

5.1.1. Confirmation application, amendment, and other documents are filled out completely, including sufficient detail on all required and applicable questions.

5.1.1.1. Informed Consent(s).

5.1.1.2. Assent Form(s), if applicable.

5.1.1.3. Recruitment materials.

5.1.1.4. CITI training from each member of the study team.

5.1.1.5. Approval letters from outside recruitment sites, if applicable.

5.1.1.6. TAMUK boilerplate statement listed on any document the participant will read.

5.1.1.7. Any other materials the IRB feels are needed to complete the review of the study.

5.1.2. If the information is not complete, the research compliance staff will contact the investigator to give them the opportunity to provide the missing information. In the event the investigator fails to make the requested changes within a reasonable amount of time and with sufficient notice, the submission may be administratively closed as incomplete

and removed from the queue as detailed in TAMUK SOP: Repositories Banking of Identifiable Specimens or Data (IRB SOP III-018).

5.1.3. Once the submission has been determined to have the necessary documents, the research compliance coordinator assigned to the IRB will follow the SOP: Information submitted for IRB TAMUK SOP: Information submitted to the IRB (SOP IRB III-003) review.

6. REFERENCES

6.1. None

Approved by: Lori Kupczynski

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